U.S. Food and Drug Administration (FDA) approves Lilly's Onswik™ (insulin efsitora alfa-gobe), a once-weekly basal insulin injection treatment for adults living with type 2 diabetes

September 24, 2026

Onswik is designed to reduce injections by over 300 per year versus once-daily basal insulin[1,2]

With Onswik, Lilly's type 2 diabetes portfolio expands to include a once-weekly basal insulin, alongside existing treatment options across insulins, incretins, oral and injectable medications

INDIANAPOLIS, Sept. 24, 2026 /PRNewswire/ -- Eli Lilly and Company today announced the U.S. Food and Drug Administration (FDA) approval of Onswik™ (insulin efsitora alfa-gobe), a once-weekly basal insulin, indicated along with diet and exercise to control high blood sugar in adults with type 2 diabetes. Onswik is designed to deliver steady basal insulin levels over a full seven days.[2]

"For over a century, Lilly has been developing insulins that transformed diabetes care for millions of people worldwide, but delays in initiating treatment and the burden of daily injections can have a real impact on patients' day-to-day experience managing type 2 diabetes," said Kenneth Custer, Ph.D., executive vice president and president, Lilly Cardiometabolic Health. "Onswik offers a new once-weekly basal insulin option for patients and reflects our continued commitment to deliver innovative treatment options that expand choice and provide greater flexibility in how people manage type 2 diabetes."

This is the fourth global approval for Onswik for adults with type 2 diabetes, following regulatory actions from the European Medicines Agency (EMA), Mexico's Federal Commission for the Protection against Sanitary Risks (COFEPRIS) and Japan's Pharmaceuticals and Medical Devices Agency (PMDA).

The FDA approval is based on data from the QWINT Phase 3 clinical trials, which evaluated the safety and efficacy of once-weekly Onswik in over 3,400 adults with type 2 diabetes. In each QWINT trial, once-weekly Onswik met the primary endpoint of non-inferior A1C reduction from baseline that was comparable to insulin glargine U-100 (glargine) or insulin degludec U-100 (degludec).[2-6]

In these clinical trials, Onswik demonstrated an overall safety profile similar to the daily basal insulins studied.[3-6] Onswik should not be used by people who have type 1 diabetes due to increased risk of severe hypoglycemia (low blood sugar). Common side effects of Onswik include low blood sugar, allergic reactions, reactions at the injection site, skin thickening or pits at the injection site (lipodystrophy), itching, rash, swelling of hands and feet, and weight gain. Please see **Indication and Safety Summary** below and full **Prescribing Information** and **Patient Information.**

Around one in eight Americans live with diabetes, and most of them have type 2 diabetes.[7] Globally by 2030, over 510 million people are expected to live with the disease and 38 million of these are expected to use insulin.[8] Insulin remains an important treatment option for many people with type 2 diabetes who do not achieve glycemic goals with other therapies.

The Onswik™ KwikPen® will be available in the U.S. in the coming months in two concentrations: 500 units/mL (contains 1,500 units total) and 1,000 units/mL (contains 3,000 units total).

For more information about Onswik, please visit www.onswik.lilly.com.

About Onswik (insulin efsitora alfa-gobe)
Onswik (insulin efsitora alfa-gobe) is a once-weekly basal insulin injection, FDA approved as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Its approval is supported by the QWINT clinical trial program, which evaluated its safety and efficacy in over 3,400 adults with type 2 diabetes. Onswik is also approved by the European Medicines Agency (EMA), the Federal Commission for the Protection against Sanitary Risks (COFEPRIS) in Mexico and Japan's Pharmaceuticals and Medical Devices Agency (PMDA) for the treatment of adults with type 2 diabetes mellitus.

About the QWINT clinical trial program
The QWINT Phase 3 global clinical development program for insulin efsitora alfa-gobe (efsitora) in diabetes began in 2022 and enrolled over 3,400 people living with type 2 diabetes across four global registration studies.

QWINT-1 (NCT05662332) was a parallel-design, open-label, treat-to-target, randomized controlled clinical trial comparing the efficacy and safety of efsitora as a once-weekly basal insulin using a fixed-dosage escalation to daily insulin glargine for 52 weeks in insulin-naïve adults with type 2 diabetes. The trial randomized 795 participants across the U.S., Argentina and Mexico to receive efsitora once weekly or insulin glargine once daily, administered subcutaneously. Participants treated with efsitora received a starting dose of 100 units of insulin, followed by escalation to fixed dosages of 150 units, 250 units and 400 units every four weeks, as needed, until achieving a target fasting blood glucose of 80-130 mg/dL. Participants with fasting blood glucose greater than 130 mg/dL on or after 16 weeks underwent additional weekly dosage adjustments as needed. The primary objective of the trial was to demonstrate non-inferiority in reducing A1C at week 52 with efsitora compared to daily use of insulin glargine.

QWINT-2 (NCT05362058) was a parallel-design, open-label, treat-to-target, randomized controlled clinical trial comparing the efficacy and safety of efsitora as a once-weekly basal insulin to insulin degludec for 52 weeks in insulin-naïve adults with type 2 diabetes. The trial randomized 928 participants across the U.S., Brazil, Canada, China, Czechia (Czech Republic), Germany, Greece, Japan, Korea, Mexico and Puerto Rico to receive efsitora once weekly or insulin degludec once daily administered subcutaneously. The primary objective of the trial was to demonstrate non-inferiority in reducing A1C at week 52 with efsitora compared to insulin degludec. The trial was also designed to assess efficacy and safety for patients using and

not using GLP-1 receptor agonists.

QWINT-3 (NCT05275400) was a multicenter, randomized, parallel-design, open-label trial comparing the efficacy and safety of efsitora as a once-weekly basal insulin to insulin degludec for 78 weeks after a three-week lead-in followed by a five-week safety follow up period, in adults with type 2 diabetes who are currently treated with basal insulin. The trial randomized 986 participants across the U.S., Argentina, Hungary, Japan, Korea, Poland, Puerto Rico, Slovakia, Spain and Taiwan to receive efsitora once weekly or insulin degludec once daily, administered subcutaneously. The primary objective of the study was to demonstrate non-inferiority in reducing A1C at week 26 with efsitora compared to insulin degludec.

QWINT-4 (NCT05462756) was a parallel-design, open-label, treat-to-target, randomized controlled clinical trial comparing the efficacy and safety of efsitora as a weekly basal insulin to insulin glargine for 26 weeks in adults with type 2 diabetes who have previously been treated with basal insulin and at least two injections per day of mealtime insulin. The trial randomized 730 participants across the U.S., Argentina, Germany, India, Italy, Mexico, Puerto Rico and Spain to receive efsitora once weekly or insulin glargine once daily, both of which were administered subcutaneously along with insulin lispro. The primary objective of the trial was to demonstrate non-inferiority in reducing A1C at week 26 with efsitora compared to insulin glargine.

INDICATION AND SAFETY SUMMARY

Onswik™ (ON-swihk) is a long-acting insulin that is used with diet and exercise to control high blood sugar in adults with type 2 diabetes mellitus.
- Onswik should not be used by people who have type 1 diabetes mellitus.
- It is not known if Onswik is safe and effective in children.

Onswik™ KwikPen® is available in 2 concentrations: U-500 and U-1,000
- U-500 (500 units/mL) prefilled pen can be injected in 5-unit increments and can deliver up to 400 units in a single injection.
- U-1,000 (1,000 units/mL) prefilled pen can be injected in 10-unit increments and can deliver up to 800 units in a single injection.

Warnings – Do not take Onswik if you:
- are having an episode of low blood sugar (hypoglycemia)
- have an allergy to insulin efsitora alfa-gobe or any of the ingredients in Onswik

Do not share your Onswik KwikPen with other people, even if the needle has been changed. You may give other people a serious infection, or get a serious infection from them.

Make sure you use the right type and dose of insulin. Always check the label on your insulin pen before each injection to avoid mix-ups with Onswik and other insulin products or injectable medicines used to treat diabetes. Pay close attention to how you select your Onswik dosage, which is different from other injectable diabetes medicines.

Always make sure that you select the correct dosage of your Onswik KwikPen as prescribed by your healthcare provider, to avoid dosing errors and accidental overdose. People who are blind or have vision problems should not use this pen without help from a person trained to use the pen.

Do not dial the maximum single dosage (400 units or 800 units) of your Onswik KwikPen, unless prescribed by your healthcare provider.

Do not use a syringe to withdraw Onswik from your pen.

Talk to your healthcare provider if you have any questions about how to correctly dose Onswik KwikPen.

Onswik may cause serious side effects that can lead to death, including:
- **Low blood sugar (hypoglycemia).** Signs and symptoms may include: dizziness or light-headedness, anxiety, irritability, mood change, confusion, shakiness, blurred vision, slurred speech, fast heartbeat, sweating, hunger, or headache.
- **Severe allergic reactions (whole body reaction).** Stop using Onswik and get medical help right away if you have any of these signs or symptoms: rash over your whole body, fast heartbeat, trouble breathing, or sweating.
- **Low potassium in your blood (hypokalemia).**
- **Heart failure.** Taking diabetes pills called thiazolidinediones or TZDs with Onswik may cause heart failure in some people. This can happen even if you have never had heart failure or heart problems before. If you have heart failure, it may get worse if you take TZDs with Onswik. Your healthcare provider should monitor you closely while you are taking TZDs with Onswik. Tell your healthcare provider if you have any new or worse symptoms of heart failure including: shortness of breath, sudden weight gain, swelling of your ankles or feet, or tiredness. Your healthcare provider may need to change or stop treatment with TZDs and Onswik.

Your insulin dose may need to be changed because of: a change in level of physical activity or exercise, weight gain or loss, increased stress, change in diet, illness, or other medicines you take.

Get emergency medical help if you have: trouble breathing, shortness of breath, fast heartbeat, swelling of your face, tongue, or throat, sweating, extreme drowsiness, dizziness, or confusion.

Common side effects
The most common side effects of Onswik include: low blood sugar (hypoglycemia), allergic reactions, reactions at the injection site, skin thickening or pits at the injection site (lipodystrophy), itching, rash, swelling of your hands and feet, and weight gain.

These are not all the possible side effects of Onswik. Tell your doctor if you have any side effects. You can report side effects at 1-800-FDA-1088 or www.fda.gov/medwatch.

Before using

Before taking Onswik, tell your healthcare provider about all your medical conditions and medicines you take, including if you:

- have liver or kidney problems.
- take diabetes medicines called TZDs.
- have heart problems. If you have heart failure, it may get worse while you take TZDs with Onswik.
- are pregnant, planning to become pregnant, or are breastfeeding. It is not known if Onswik may harm your unborn or breastfeeding baby.
- take prescription or over-the-counter medicines, vitamins, or herbal supplements.

Before you start Onswik, talk to your healthcare provider about low blood sugar and how to manage it.

How to take

- Read the **Instructions for Use** that come with your Onswik KwikPen.
- **Your healthcare provider should show you how to use Onswik KwikPen before you use it for the first time.**
- Take Onswik exactly as your healthcare provider tells you.
- Know the type, strength and amount of insulin you take. **Do not change the type of insulin unless** your healthcare provider tells you to.
- Inject Onswik 1 time each week, on the same day of the week.
- If you need to change the day of the week, you may do so at least 4 days since your last dose. Then continue to inject Onswik 1 time each week on the new day you have chosen.
- **If you miss a dose of Onswik,** take the missed dose as soon as possible within 4 days (96 hours) after the missed dose, then continue your regular weekly dose schedule. If more than 4 days have passed, skip the missed dose and take your next dose on the regularly scheduled day **or** take the missed dose then change your regular weekly dose schedule to start 1 week after your missed dose was injected.
- **If you accidentally take your 1-time starting dose more than 1 time (2 times in a row) or take your weekly dose more than 1 time in the same week, skip your next week's dose.**
- Inject Onswik under the skin (subcutaneously) of your stomach area, buttocks, thigh or back of the upper arms.
- **Do not** use Onswik in an insulin pump or inject Onswik into your vein or muscle.
- **Change (rotate) your injection sites within the area you choose with each dose. Do not** use the exact same spot for each injection. **Do not** inject into skin that is thickened or has pits or lumps. **Do not** inject into skin that is tender, bruised, scaly, or hard or into scars or damaged skin.
- Always use a new needle for each injection. If your needle is blocked, get a new needle. **Do not** reuse or share your needles with other people.
- **Do not** use a syringe to remove the solution from the pen.
- **Do not** dilute or mix Onswik with another insulin or liquid medicine.
- **Check your blood sugar levels.** Ask your healthcare provider what your blood sugar levels should be and when you should check your blood sugar levels.

While taking Onswik, do not:

- drive or operate heavy machinery, until you know how Onswik affects you.
- drink alcohol or use prescription or over-the-counter medicines that contain alcohol.

Learn more

Onswik is a prescription medicine available as a 500 units/mL or 1,000 units/mL injection in a 3 mL pre-filled, single-patient-use pen. For more information, call 1-800-545-5979 or go to onswik.lilly.com.

This summary provides basic information about Onswik but does not include all information known about this medicine. Read the information that comes with your prescription each time your prescription is filled. This information does not take the place of talking with your doctor. Be sure to talk to your doctor or other healthcare provider about Onswik and how to take it. Your doctor is the best person to help you decide if Onswik is right for you.

EF CON BS SEP2026

Endnotes and References

1. Based on approximate number of injections per year for Onswik (52 injections) vs a once-daily basal insulin (365 injections). This information is not intended to make a comparison of safety or efficacy.
2. Onswik. Prescribing Information. Lilly USA, LLC.
3. Rosenstock J, Bailey T, Connery L, et al. Weekly fixed-dose insulin efsitora in type 2 diabetes without previous insulin therapy. *N Engl J Med*. 2025;393(4)(Incl suppl append):325-335. doi:10.1056/NEJMoa2502796
4. Wysham C, Bajaj HS, Del Prato S, et al. Insulin efsitora versus degludec in type 2 diabetes without previous insulin

treatment. *N Engl J Med*. 2024;391(23)(Incl suppl mat):2201-2211. doi:10.1056/NEJMoa2403953
5. Philis-Tsimikas A, Bergenstal RM, Bailey TS, et al. Once-weekly insulin efsitora alfa versus once-daily insulin degludec in adults with type 2 diabetes currently treated with basal insulin (QWINT-3): a phase 3, randomised, non-inferiority trial. *Lancet*. 2025;405(10497)(Incl suppl mat):2279-2289. doi:10.1016/S0140-6736(25)01044-X
6. Blevins T, Dahl D, Pérez Manghi FC, et al. Once-weekly insulin efsitora alfa versus once-daily insulin glargine U100 in adults with type 2 diabetes treated with basal and prandial insulin (QWINT-4): a phase 3, randomised, non-inferiority trial. *Lancet*. 2025;405(10497):2290-2301. doi:10.1016/S0140-6736(25)01069-4
7. Centers for Disease Control and Prevention. About type 2 diabetes. CDC. Accessed August 10, 2026. https://www.cdc.gov/diabetes/about/about-type-2-diabetes.html
8. Basu S, Yudkin JS, Kehlenbrink S, et al. Estimation of global insulin use for type 2 diabetes, 2018–30: a microsimulation analysis. *Lancet Diabetes Endocrinol.* 2019;7(1):25-33. doi:10.1016/S2213-8587(18)30303-6. Available from: https://www.thelancet.com/journals/landia/article/PIIS2213-8587%2818%2930303-6/abstract

About Lilly
Lilly is a medicine company turning science into healing to make life better for people around the world. We've been pioneering life-changing discoveries for 150 years, and today our medicines help tens of millions of people across the globe. Harnessing the power of biotechnology, chemistry and genetic medicine, our scientists are urgently advancing new discoveries to solve some of the world's most significant health challenges: redefining diabetes care; treating obesity and curtailing its most devastating long-term effects; advancing the fight against Alzheimer's disease; providing solutions to some of the most debilitating immune system disorders; and transforming the most difficult-to-treat cancers into manageable diseases. With each step toward a healthier world, we're motivated by one thing: making life better for millions more people. That includes delivering innovative clinical trials that reflect the diversity of our world and working to ensure our medicines are accessible and affordable. To learn more, visit Lilly.com and Lilly.com/news, or follow us on Facebook, Instagram, and LinkedIn. P-LLY

Cautionary Statement Regarding Forward-Looking Statements
This press release contains forward-looking statements (as that term is defined in the Private Securities Litigation Reform Act of 1995) about Onswik as a treatment for adults with type 2 diabetes and reflects Lilly's current beliefs and expectations. However, as with any pharmaceutical product, there are substantial risks and uncertainties in the process of drug research, development, and commercialization. Among other things, there is no guarantee that future study results will be consistent with study results to date, that Onswik will receive additional regulatory approvals, or that Onswik will be commercially successful. For further discussion of these and other risks and uncertainties that could cause actual results to differ from Lilly's expectations, see Lilly's Form 10-K and Form 10-Q filings with the United States Securities and Exchange Commission. Except as required by law, Lilly undertakes no duty to update forward-looking statements to reflect events after the date of this release.

Trademarks and Trade Names
All trademarks or trade names referred to in this press release are the property of the company, or, to the extent trademarks or trade names belonging to other companies are referenced in this press release, the property of their respective owners. Solely for convenience, the trademarks and trade names in this press release are referred to without the ® and ™ symbols, but such references should not be construed as any indicator that the company or, to the extent applicable, their respective owners will not assert, to the fullest extent under applicable law, the company's or their rights thereto. We do not intend the use or display of other companies' trademarks and trade names to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

Refer to: Rachel Sorvig; sorvig_rachel@lilly.com (Media)
Michael Czapar; czapar_michael_c@lilly.com (Investors)

View original content to download multimedia:https://www.prnewswire.com/news-releases/us-food-and-drug-administration-fda-approves-lillys-onswik-insulin-efsitora-alfa-gobe-a-once-weekly-basal-insulin-injection-treatment-for-adults-living-with-type-2-diabetes-302888473.html

SOURCE Eli Lilly and Company